HH

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,844	02/25/2002	Juan Yguerabide	11032-018-999	7432

20583 7590 08/25/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
YU, MELANIE J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,844	YGUERABIDE ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,16-20,27,29-36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,16-20,27,29-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 June 2006 has been entered.

Withdrawn Rejections

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 4, 18, 31-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 6,171,793) in view of Chenchik et al. (US 6,287,768).

Phillips et al. teach a method for providing an extended linear dynamic range in an analyte assay comprising: detecting integrated light signals from one or more assay sites

with a sensor having a dynamic range, wherein the integrated light intensity fluorescence signal collected from at least one assay site exceeded the dynamic range of the sensor (the probe arrays comprise a plurality of sites, col. 7, lines 1-8; col. 4, lines 42-47; scanned areas where light was so intense and exceeded the saturation level and produced a saturated, constant value, col. 9, lines 13-20; partially invalid data obtained above intensity at which the scanner saturates, col. 9, lines 46-49; first data set, col. 10, lines 43-45); applying at least one optical filter having an optical density to provide a reduced-intensity fluorescence integrated light signal that does not exceed the dynamic range of the sensor, the reduced intensity fluorescence light signal is from at least one of the at least one assay site that produced an integrated light signal that exceeded the dynamic range of the sensor (light is detected at a first and second wavelength at each site, col. 4, lines 42-54, which is performed by including filters to detect at the specified wavelengths col. 6, lines 58-61, and a linear relationship is present between the signals and the integrated light intensity fluorescence, col. 9, lines 41-59; col. 9, lines 21-34; filter applied to obtain reduced-intensity signal at 530 nm, col. 9, line 61-col. 10, line 4; col. 6, lines 58-61); detecting a second set of integrated light intensity fluorescence signals from the light scattering particles at the one or more assay sites with the sensor, the second set comprising the reduced-intensity fluorescence integrated light signals (reduced intensity signals are detected at 530 nm and produces a curve which is in cutoff for low light intensities and is therefore reduced intensity, col. 10, lines 1-4 and 13-17, second data set, col. 10, lines 45-46); converting the reduced-intensity fluorescence integrated light signals to a scaled signal using a predetermined conversion factor related to the optical density of the optical filter (col. 4, lines 55-62; conversion factor is from curves produced from first and second data sets at two different maximum wavelengths, which is related to the optical density of the optical filter which regulates the maximum wavelength, col. 10, lines 27-35; correlation

calculated, col. 10, lines 49-61; scale factor if the results are linear is 200 and is therefore pre-determined and fixed, col. 10, lines 26-35); and combining the scaled signal with the first set of integrated light intensity fluorescence signals to provide an extended dynamic range (col. 9, lines 50-60; col. 10, lines 62-67). Phillips et al. fail to teach detection of scattered light from light scattering particles and integrated scattered light signals.

Chenchik et al. teach that either fluorescent markers or light scattering particles can be used for optical detection (col. 16, lines 36-47), in order to provide labeling for molecules.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Phillips et al., substituting light scattering particles for fluorescent markers as taught by Chenchik, which would result in optical detection of scattered light intensity signals produced by light scattering particles at specified wavelengths instead of optical detection of fluorescent light intensity signals. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection technique and since only the expected labeling effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Regarding claim 18, Phillips et al. teach converting the one or more reduced-intensity signals to one or more scaled signals by multiplying the one or more reduced intensity signals by the conversion factor of the at least one filter (conversion factor relies on the optical filter used to filter out wavelengths above 530 nm, and therefore conversion factor is related to the optical density of the optical filter, col. 10, lines 26-35).

With respect to claims 31-36, Phillips et al. teach further forming an image of one or more assay sites with the combined scaled signal and first set of integrated light intensity

signals (col. 11, lines 15-30, comparison of image result before and after conversion shown in figures 7 and 13, respectively) comprising the steps of identifying background portions of the image and removing signals corresponding to the background portions of the image (background signals are identified and removed from detected signal for reduced-intensity signal, col. 9, lines 35-49). Phillips et al. also teach the sensor being a photomultiplier tube (col. 6, lines 51-57). Phillips et al. further teach a the at least one or more assay sites being separately addressable assay sites (col. 6, lines 62-67), associated with a microarray (col. 5, lines 49-53), and present in a sample of a cell (col. 8, lines 42-51).

Regarding claim 38, Phillips et al. teach after a step of detection a second integrated signal, repeating: applying at least one optical filter having an optical density that is different than the at least one optical filter to provide a reduced-intensity integrated light signal that does not exceed the dynamic range of the sensor, the reduced-intensity light signal from at least one of the at least one assay sites that produced an integrated light signal that exceeded the dynamic range of the sensor; and detecting another set of integrated light intensity signals from the light at the one or more assay sites with the sensor, the another set comprising the reduced-intensity integrated light signals of the repeated step (if it is desired to further increase the dynamic range three or more scans with the wavelength at suitably selected different values, therefore an optical filter with a different optical density would be applied to provide a reduced intensity integrated light signal and scanning would provide detection and a data set with the optical filter with a different optical density, col. 12, lines 39-47).

4. Claims 16, 17, 19, 20, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 6,171,793) in view of Chenchik et al. (US 6,287,768), as applied to claim 4, and further in view of Bartz (US 5,350,922).

Regarding claims 16 and 19, Phillips et al. in view of Chenchik et al., as applied to claim 4, teach a method for providing an extended linear dynamic range in an analyte assay and a conversion factor determined from a transmission curve for the filter (conversion factor is determined from a transmission curve that is generated from measurements at 530 nm and 570 nm which are provided using an optical filter, therefore the conversion factor is determined based on a transmission curve for the filter, col. 10, lines 26-35) based on measurements of transmission of light through the filter (filter is used to generate a curve for 530 nm, col. 6, lines 58-61). However, Phillips et al. fail to teach one or more of the filters being a bandpass interference filter and a white light source.

Bartz teaches a bandpass interference filter (col. 7, lines 8-12) and a white light source (col. 6, lines 1-12), in order to pass corresponding wavelength bands by fiber optic probes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Phillips et al., a bandpass interference filter, a white light source and light from light scattering particles as taught by Bartz, in order to reduce the optical and electronic signal to noise ratio and provide a precise filter that detects below a specified wavelength.

Regarding claim 17, the transmission curve for the filter is wavelength dependent (transmission curve is generated from scanning at 570 nm and 530 nm, and is therefore wavelength-dependent, col. 10, lines 5-12).

With respect to claim 27, Bartz teaches light transmitted by filters using a white light source (col. 6, lines 1-12). Bartz further teaches integrated scattered light intensity signals from light scattering particles comprising light scattered by the light scattering particles (col. 3, lines 26-30).

With respect to claims 29 and 30, Bartz teaches an extended range comprising integrated scattered light intensity signals quantified over at least six orders of magnitude (col. 3, lines 47-50), and the dynamic range extended by at least one order of magnitude over the dynamic range of an assay without the extension of the dynamic range (col. 3, lines 41-50; col. 4, lines 49-54), and the dynamic range being linear (col. 3, lines 41-46).

Regarding claim 20, Phillips et al., as applied to claim 4, fail to teach the amount of light transmitted by one or more filters. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 20 are for any particular purpose or solve any stated problem, and the prior art teaches that the light transmitted by one or more filters can be varied in order to prevent direct transmission of light from the light source to the detector, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the detection of scattered light art.

Response to Arguments

5. Applicant's arguments filed 19 June 2006 have been fully considered but they are not persuasive. At pages 6-8, applicant argues that Phillips et al. fail to teach a predetermined conversion factor. However, in response to applicant's arguments, Phillips et al. teach that

when the results are linear the scaling factor is 200, which is a predetermined conversion factor. Applicant argues that Chenchik and Bartz fail to teach a predetermined conversion factor. In response to applicant's arguments, it is noted that Bartz and Chenchik are not relied upon for this limitation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Yu

Melanie Yu
Patent Examiner
Art Unit 1641

Long Le

LONG V. LE 08/13/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600